#### APPENDIX X.X.X.

# DRAFT GUIDELINES FOR THE CONTROL OF AQUATIC ANIMAL HEALTH HAZARDS IN AQUATIC ANIMAL FEED

Article X.X.X.1.

#### Introduction

One of the key objectives of the Aquatic Code is to help OIE Members trade safely in aquatic animals and aquatic animal their products by developing relevant aquatic animal health measures. These guidelines address aquatic animal health hazards in aquatic animal feed. A key objective is to prevent the spread, via aquatic animal feed, of diseases from an infected country, zone or compartment to a free country, zone or compartment.

These guidelines do not for the moment address food safety issues in detail as this is not within the mandate of the OIE Aquatic Code Animal Health Standards Commission (hereafter referred to as the Aquatic Animals Commission).

These Guidelines should be read in conjunction with relevant recommendations of the OHE Terrestrial Animal Health Code (under study Appendix containing recommendations on animal feed). The Food and Agriculture Organization of the United Nations (FAO) has published recommendations relevant to terrestrial and aquatic animal feed (Technical Guidelines for Responsible Fisheries – Aquaculture Development: 1. Good aquaculture feed manufacturing practice. FAO 2001; Draft Good Practices for the Animal Feed Industry – Implementing the Codex Alimentarius' Code of Practice on Good Animal Feeding, IFIF/FAO [In preparation]) and there is a Codex Alimentarius Commission (CAC) standard (Code of Practice on Good Animal Feeding [CAC/RCP 54-2004]). Members are encouraged to consult these publications.

Key considerations relevant to aquatic animal feeds are as follows:

- 1. Concentration of *aquaculture establishments* and intensive rearing causes a concentration of *aquatic* animals, feed and faecal matter in time and space and this heightens the risk of disease transmission, whether the pathogen enters the culture system via feed or other means.
- 2. For many *aquatic animal* species, predation (including cannibalism) is their natural way of feeding in their natural habitat.
- 3. Historically, animal proteins used in *feed* were mainly sourced from the marine environment, due to the nutritional needs of *aquatic animals* and for reasons of economy. This practice increases the <u>risk of</u> disease <u>risks transmission</u>, especially when *aquatic animals* are fed <u>with</u> live or whole *aquatic animals* of the same or related species. There are many examples of this type of practice, e.g. early stage crustaceans fed on *Artemia* species and *aquaculture* tuna fed on whole wild caught fish.

- 4. The usage of *feed* in moist <u>form (moisture content equal to or greater than 70%)</u>, semi-moist <u>form (moisture content between 15 and 70%)</u>, and dry form <u>(a moisture content equal to or less than 15%)</u> implies different levels of risk due to the processing applied to the *feed*.
- 5. With the increasing number of species being farmed (especially marine finfish), the use of *live* <u>feed</u> and moist *feed* has increased. It is likely that these industries will in future use formulated *feed* as appropriate technologies are developed.
- 6. Hazards may be transmitted from feed to aquatic animals via direct or indirect means. Direct transmission occurs when the cultured species consumes feed containing a pathogenic agent (e.g. shrimp larvae consuming rotifer infected with white spot syndrome virus) while indirect transmission refers to pathogens in feed entering the aquatic environment or infecting non target species, and thereby establishing a mechanism for indirect infection of the species of commercial interest. Pathogens that are less host-specific (e.g. white spot syndrome virus, Vibrio species) present a greater risk of indirect transmission as they can establish reservoirs of infection in multiple species.
- 7. As new species become the subject of *aquaculture*, new pathogens emerge in association with these hosts. The expression of disease may be facilitated by culturing species under intensive and novel conditions. Also, it is necessary to conduct research and develop new *feed* (and *feed ingredients*) that are appropriate to the species and its culture system. As more and more *aquatic animal* species are being cultured, it is difficult to make recommendations for all disease agent/host species combinations.

Article X.X.X.2.

# Scope

These guidelines document risk mitigation measures, including traceability and certification, to deal with aquatic animal health risks associated with trade in aquatic animal feeds and feed ingredients. They recommends the control of hazards through adherence to recommended practices during the production (harvest, handling, storage, processing and distribution) and use of both commercial and on-farm produced feed (and feed ingredients) for aquatic animals. Hazards include pathogens that cause OIE-listed diseases referred to oin this Aquatic Code and other agents that cause an adverse effect on animal and/or public health. While aquatic animals grown for food are the main focus, the same principles apply to feed for aquatic animals used for other purposes.

Article X.X.X.3.

#### **Definitions**

# Dry feed

<u>mMeans feed that has a moisture content equal to or less than 15%.</u>

#### Feed

<u>mM</u>eans any material (single or multiple), whether processed, semi-processed or raw that is intended to be fed directly to <u>food-producing</u> <u>aquatic</u> animals.

#### Feed additives

<u>mM</u>eans any ingredient intentionally added in micro-amounts not normally consumed as *feed* by itself, whether or not it has nutritional value, which affects the characteristics of *feed* or

animal products. Micro-organisms, enzymes, acidity regulators, trace elements, vitamins, substances used to attract *aquatic animals* to feed and promote *feed* intake, pigments, synthetic binders, synthetic amino acids, antioxidants and other products fall within the scope of this definition, depending on the purpose of use and method of administration. This excludes veterinary drugs.

# Feed ingredient

mMeans a component, part or constituent of any combination or mixture making up a feed, including feed additives, whether or not it has a nutritional value in the animal's diet. Ingredients may be of terrestrial or aquatic, plant or animal origin and may be organic or inorganic substances.

#### Fish solubles

<u>mMeans a by-product of the fish oil production system, comprising the product remaining when water is drawn off (evaporated) from the residual aqueous phase.</u>

#### Hazard

<u>m</u>Means a biological, chemical or physical agent in a *feed* or a *feed ingredient* with the potential to cause an adverse effect on animal or public health.

#### Live feed

<u>mM</u>eans live farmed or wild caught animals and algae used as *feed* for *aquatic animals*. Live feed is often fed to *aquatic animal* species at an early life-stage and to *aquatic animal* species that have been cultured for a relatively short time.

#### Meal

<u>mM</u>eans a product derived from an *aquatic animal* that has been ground and heat processed to reduce the moisture content to less than 10%.

#### Medicated feed

mMeans any feed which contains a veterinary drug administered to food producing animals, for therapeutic or prophylactic purposes or for modification of physiological functions.

# Moist (or wet) feed

mMeans feed that has a moisture content equal to or greater than 70%.

#### Semi-moist feed

mMeans feed that has a moisture content between 15 and 70%.

Article X.X.X.4.

# General principles

#### 1. Roles and responsibilities

The Competent Authority has the legal power to set and enforce regulatory requirements related to animal feed, and has final responsibility for verifying that these requirements are met. The Competent Authority may establish regulatory requirements for relevant parties, including requirements to provide information and assistance.

It is a particular responsibility of the Competent Authority to set and enforce the regulatory requirements pertaining to the use of veterinary drugs, aquatic animal disease control and the

food safety aspects that relate to the management of live aquatic animals on farm.

Those involved in the production and use of animal feed and feed ingredients have the responsibility to ensure that these products meet regulatory requirements. All personnel involved in the harvest, manufacture, storage and handling of feed and feed ingredients should be adequately trained and aware of their role and responsibility in preventing the spread of hazards. Appropriate contingency plans should be developed in case of a feed-borne disease outbreak of disease. Equipment for producing, storing and transporting feed should be kept clean and maintained in good working order.

Private *veterinarians* and others (e.g. laboratories) providing specialist services to producers and to the feed industry may be required to meet specific regulatory requirements pertaining to the services they provide (e.g. disease reporting, quality standards, transparency).

#### 2. Regulatory standards for feed safety

All *feed* and *feed ingredients* should meet regulatory standards for *feed* safety. In defining limits and tolerances for *hazards*, scientific evidence, including the sensitivity of analytical methods, and on the characterisation of risks, should be taken into account.

# Risk analysis

Internationally accepted principles and practices for *risk analysis* (see Section 1.4. of the *Aquatic Code* and relevant Codex texts) should be used in developing and applying the regulatory framework.

A generic *risk analysis* framework should be applied to provide a systematic and consistent process for managing *hazards*.

# 4. Good practices

Where national guidelines exist, good *aquaculture* practices and good manufacturing practices (including good hygienic practices) should be followed. Countries without such guidelines are encouraged to develop them.

Where appropriate, Hazard Analysis and Critical Control Point<sup>2</sup> (HACCP; as defined in the Annex to the Recommended International Code of Practice on General Principles of Food Hygiene [CAC/RCP 1-1969]) principles should be followed to control *hazards* that may occur in *feed*.

# 5. Relationship between prions and aquatic animal species

Scientific knowledge is lacking on the relationship between prions and *aquatic animal* species. There is no evidence to suggest that the use of terrestrial animal by-products as ingredients in *aquatic animal feed* gives rise to risks in respect of prion diseases. More scientific information is

If at the national level, there are specific food-safety or animal health regulations related to genetically modified organisms, these should be taken into account in relation to feed and feed ingredients as these products form an important part of the feed chain.

Hazard Analysis and Critical Control Point, as defined in the Annex to the Recommended International Code of Practice on General Principles of Food Hygiene (CAC/RCP 1-1969).

desirable to enable *aquaculture* industries to utilise more terrestrial animal by-products as a means of reducing dependency on aquatic protein and lipid sources.

# 6. Bioaccumulation

Heavy metals, dioxins and polychlorinated biphenyls (PCB) persist in fatty tissues and therefore tend to accumulate through the food chain.

# 7. Geographic and environmental considerations

Aquatic and terrestrial harvest areas for *feed* should not be located in proximity to sources of animal health or food safety *hazards*. Where this cannot be avoided, preventive measures should be applied to control risk. The same recommendations apply for the processing of *feed* and the location of *aquaculture establishments*.

Aquatic animal health considerations include factors such as disease status, location of quarantined premises, existence of processing plants without proper biosecurity measures and the existence of gones/compartments of specified health status.

Public health considerations include factors such as industrial operations and waste treatment plants that generate pollutants and other hazardous products. The potential accumulation of pollutants in the food chain through *feed* needs to be considered.

# 8. Zoning and compartmentalisation

Feed is an important components of biosecurity and needs to be considered when defining a *compartment* or *zone* in accordance with Chapter 1.4.4. of the *Aquatic Code*.

#### 9. <u>Sampling and analysis</u>

Sampling and analytical protocols <u>for feed</u> should be based on scientific principles and procedures, and OIE standards where applicable.

#### 10. <u>Labelling</u>

Labelling should be clear and informative on how the *feed* and *feed ingredients* should be handled, stored and used and should comply with regulatory requirements. Labelling should provide for trace-back.

See Section 4.2. of the Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004).

# 11. Design and management of inspection programmes

In meeting animal and public health objectives prescribed in national legislation or required by *importing countries*, *Competent Authorities* contribute through the direct performance of some tasks or through the auditing of animal and public health activities conducted by other agencies or the private sector.

Operators in the *feed* and *feed ingredients* business and other relevant industries should implement procedures to ensure compliance with regulatory standards for harvest, handling, storage, processing, distribution and use of *feed* and *feed ingredients*. Operators have the primary responsibility for implementing systems for process control. Where such systems are applied,

the Competent Authority should verify that they meet all regulatory requirements.

# 12. Assurance and certification

Competent Authorities are responsible for providing assurances domestically and to trading partners that regulatory requirements have been met.

#### 13. Hazards associated with aquatic animal feed

# a) Biological hazards

Biological hazards that may occur in *feed* and *feed ingredients* include agents such as bacteria, viruses, fungi and parasites. The scope of these guidelines covers is limited to the OIE-listed diseases referred to in this Aquatic Code and other agents that cause an adverse effect on animal and/or public health.

# b) <u>Chemical hazards</u>

Chemical hazards that may occur in *feed* and *feed ingredients* include naturally occurring chemicals (such as mycotoxins, gossypol and free radicals), industrial and environmental contaminants (such as heavy metals, dioxins and PCBs), residues of veterinary drugs and pesticides and radionuclides.

# c) Physical hazards

Physical hazards that may occur in *feed* and *feed ingredients* include foreign objects (such as pieces of glass, metal, plastic or wood).

#### 14. Cross-contamination

It is important to avoid cross-contamination during the manufacture, storage, distribution (including transport) and use of *feed* and *feed ingredients*. Appropriate provisions should be included in the regulatory framework. Scientific evidence, including the sensitivity of analytical methods and on the characterisation of risks, should be drawn upon in developing this framework.

Procedures such as flushing, sequencing and physical clean-out should be used to avoid cross-contamination between batches of *feed* or *feed ingredients*. National regulations should be followed in order to avoid the use of unauthorised *feed ingredients* with a risk of cross-contamination.

#### 15. Antimicrobial resistance

Concerning the use of antimicrobials in animal *feed* refer to Section X.X.X. of the *Aquatic Code* (under study).

#### 16. Management of information

The *Competent Authority* should establish requirements for the provision of information by the private sector in accordance with the on regulatory framework.

The private sector should maintain records, in a readily accessible form, on the production, distribution, importation and use of *feed* and *feed ingredients*. These records are required to

facilitate the prompt trace-back of *feed* and *feed ingredients* to the immediate previous source, and trace-forward to the next/subsequent recipients, to address *aquatic animal* health and/or public health concerns. The private sector should provide information to the *Competent Authority* in accordance with the regulatory framework.

Animal identification (in the case of *aquatic animals* this will normally be on a group basis) and traceability are tools for addressing animal health and food safety risks arising from animal *feed* (see Section 3.5. of the *Terrestrial Animal Health Code*; Section 4.3 of CAC/RCP 54-2004).

Article X.X.X.5.

# Pathogens in feed

- 1. Pathogens can be introduced into *feed* in the following ways:
  - a) via the harvest of infected aquatic animals;
  - b) during storage, processing and transport, due to poor hygienic practices, the presence of pests, or residues of previous batches of *feed* remaining in processing lines, containers or transport *vehicles*.
- 2. Aquatic animals can be exposed to pathogens in feed in the following ways:
  - a) Direct exposure

The use of unprocessed *feed* derived from *aquatic animals* to feed *aquatic animals* presents a direct route of exposure, particularly when feeding whole *aquatic animals* and unprocessed products of *aquatic animals* to animals of the same species. For example feeding salmonid *offal* to salmonids or feeding rotifers or *Artemia* species to crustaceans presents a heightened risk of disease transmission.

b) Indirect exposure

Pathogens in *feed* may be transmitted to *aquatic animals* in *aquaculture* and wild *aquatic animals* via contamination of the environment or *infection* of non-target species.

Article X.X.X.6.

#### Chemical agents in feed

[under study]

Article X.X.X.7.

# Physical agents in feed

[under study]

#### Article X.X.X.8.

# Recommended approaches to risk mitigation

#### 1. Commodities

#### a) Safe commodities

The following *commodities* undergo extensive processing such as heat treatment, acidification, extrusion and extraction. There is a negligible risk that pathogens will survive in such products if they have been produced in accordance with normal commercial practice:

- i) fish oil;
- ii) crustacean oil;
- iii) fish solubles; (a by-product of the fish oil production system, comprising the product remaining when water is drawn off (evaporated) from the residual aqueous phase);
- iv) fish meal;
- v) crustacean meal;
- vi) squid <mark>meal</mark> and squid liver-<mark>meal</mark>;
- vii) bivalve meal;
- viii) finished feed (e.g. flake, pelleted and extruded feed).

For these commodities, Competent Authorities should not require conditions in relation to aquatic animal diseases, regardless of the aquatic animal health status of the exporting country, zone or compartment.

#### b) Other commodities

Competent Authorities should consider the following risk mitigation measures:

- i) sourcing feed and feed ingredients from a disease free country, free zone or free compartment; or
- ii) confirmation (e.g. by testing) that pathogens are not present in the commodity; or
- iii) treatment (e.g. by heat or acidification) of the *commodity* using a method approved by the *Competent Authority* to inactivate pathogens; or
- iv) use of *feed* only in *populations* that are not susceptible to the pathogen(s) in question and where *aquatic animals* that are susceptible to the pathogen(s) in question will not come into contact with the *feed* or its waste products.

In addition, risks associated with the disposal of effluents and waste material from *feed* processing plants and *aquaculture establishments* should be considered.

#### c) Whole fish (fresh or frozen)

The practice of trading fresh or frozen whole marine fish for use as <u>aquatic animal</u> feed presents a risk of introducing diseases into <u>populations</u>. <u>Risk mitigation measures include</u> sourcing fish only from stocks where there is no evidence of <u>infection</u> with any of the <u>OIE-listed diseases</u> or treatments that inactivate <u>aquatic animal</u> pathogens. Given the difficulty of imposing effective <u>risk</u> mitigation measures, this practice is not recommended.

# Feed production

To prevent contamination by pathogens during production, storage and transport of *feed* and *feed ingredients*:

- i) flushing, sequencing or physical clean-out of manufacturing lines and storage facilities should be performed between batches as appropriate;
- ii) buildings and equipment for processing and transporting *feed* and *feed ingredients* should be constructed in a manner that facilitates hygienic operation, maintenance and cleaning and prevents contamination;
- iii) in particular, feed manufacturing plants should be designed and operated to avoid crosscontamination between batches;
- iv) processed *feed* and *feed ingredients* should be stored separately from unprocessed *feed ingredients*, under appropriate storage conditions;
- v) feed and feed ingredients, manufacturing equipment, storage facilities and their immediate surroundings should be kept clean and pest control programmes should be implemented;
- vi) measures to inactivate pathogens, such as heat treatment or the addition of authorised chemicals, should be used where appropriate. Where such measures are used, the efficacy of treatments should be monitored at appropriate stages in the manufacturing process;
- vii) labelling should provide for the identification of *feed* and *feed ingredients* as to the batch/lot and place and date of production. To assist in tracing *feed* and *feed ingredients* as may be required to deal with animal disease incidents, labelling should provide for identification by batch/lot and place and date of production.

# 3. <u>Importing countries</u>

Competent Authorities should consider the following measures:

- i) imported *feed* and *feed ingredients* should be delivered to feed manufacturing plants or *aquaculture* facilities for processing and use under conditions approved by the *Competent Authority*;
- ii) effluent and waste material from feed manufacturing plants and aquaculture facilities should

be managed under conditions approved by the *Competent Authority*, including, where appropriate, treatment before discharge into the aquatic environment;

- iii) feed that is known to contain pathogens should only be used in a zone or compartment that does not contain species susceptible to the disease in question;
- iv) the importation of raw unprocessed *feed* derived from *aquatic animals* to feed *aquatic animal* species should be avoided where possible.

Article X.X.X.9.

# Certification procedures for feeds and feed ingredients of aquatic animal origin

When importing feed and feed ingredients of aquatic animal origin other than those mentioned in Article X.X.X.8. X. (see Article with safe commodities, currently point 1a) of Article X.X.X.8. I, the Competent Authority of the importing country should require that the consignment be accompanied by an international aquatic animal health certificate issued by the Competent Authority of the exporting country (or a certifying official approved by the importing country).

This certificate should certify:

- i) that feed and feed ingredients of aquatic animal origin were obtained from a country, zone or compartment that is free from relevant aquatic animal diseases<sup>3</sup>; or
- ii) that *feed* and *feed ingredients* of *aquatic animal* origin were tested for relevant *aquatic animal diseases*<sup>4</sup> and shown to be free of these *diseases*; or
- that feed and feed ingredients of aquatic animal origin have been processed to ensure that they are free of relevant aquatic animal diseases.

Specific provisions for <u>OIE-listed</u> diseases referred to in this <u>Aquatic Code</u> may be found in relevant disease chapters of the <u>Aquatic Code</u>.

Article X.X.X.10.

# Risk chart of pathogen transmission and contamination through harvest, manufacture and use of aquatic animal feed

Figure 1 illustrates the possible pathways for transmission of pathogens within the feed production and utilisation process.

Feed ingredients of aquatic origin used in aquaculture can be a source of pathogens (viruses, bacteria and parasites) to cultured aquatic animal species. In aquaculture establishments pathogens in feed can infect the animals directly (via consumption of feed) or indirectly via environmental sources. Live feed and moist feed are more likely to contain pathogens because their ingredients are either in a raw state or subject to minimal treatment.

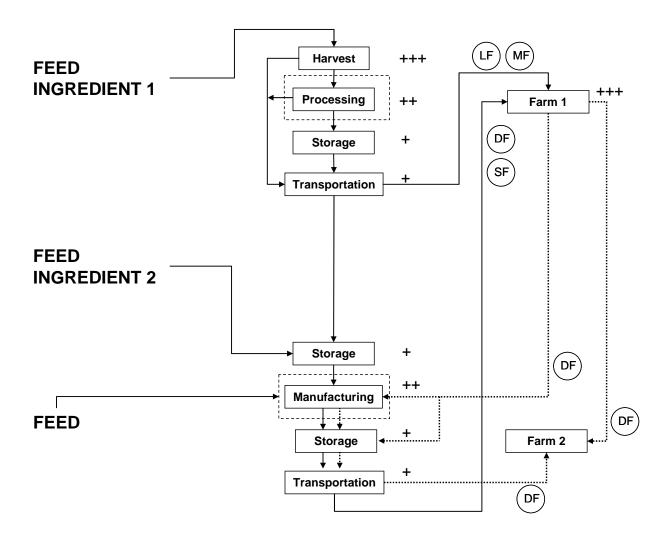
Conditions agreed between the Competent Authorities of the importing and exporting countries in accordance with the recommendations of the OIE Aquatic Animal Health Code.

Conditions agreed between the Competent Authorities of the importing and exporting countries in accordance with the recommendations of the OIE Aquatic Animal Health Code.

Feed and feed ingredients harvested from infected countries, zones or compartments may have a high pathogen load. Feed and feed ingredients from these sources should be processed (e.g. using heat or chemical treatments) to reduce, or eliminate, the pathogen load. After processing care should be taken to avoid post processing contamination during storage and transportation of these commodities. For example, when two or more batches of ingredients of different sanitary status are handled, stored and/or transported together without appropriate biosecurity measures, there is a risk of crosscontamination of the feed.

An *aquaculture* facility can also be a source of pathogens in *aquatic* <u>animal</u> feed. For example, feed can be contaminated with pathogens through poor hygiene practices at an infected <u>aquaculture</u> establishment. If the feed is redistributed from the <u>aquaculture</u> facility to the manufacturing facility for recycling, or distributed to another farm, pathogens can be transferred to other <u>aquaculture</u> establishments.

Figure 1: RISK CHART OF PATHOGEN TRANSMISSION AND CONTAMINATION THROUGH HARVEST, MANUFACTURE AND USE OF AQUATIC ANIMAL FEED



LF: Live feed	
MF: Moist feed	
SF: Semi-moist feed	Possibility for risk reduction
DF: Dry feed	
+++: High risk of pathogen presence	
++: Moderate risk of pathogen presence	
+: Low risk of pathogen presence	Redistribution or recycling of finished feed

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